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Regulation of Pharmaceutical Industry Interactions with Health Care Professionals

An Overview of the South Korean Experience

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Abstract

In October 2006, the Korean Fair Trade Commission (“KFTC”), the country’s antitrust and fair trade authority, began an investigation into illicit practices in the pharmaceutical industry. The investigation was unprecedented in terms of the number of companies investigated and found guilty (17 and counting), the scope of activities and volume of evidence reviewed, and the amount of fines ultimately imposed (no company that was investigated escaped fines, for a cumulative total of approximately USD 35 million) for violations consisting mostly of illicit benefits provided by companies to healthcare professionals or medical institutions, which the KFTC found to be “unfair customer solicitation” prohibited under the country’s fair trade laws. In the aftermath of KFTC’s successful enforcement actions, other governmental agencies jumped on the anti-kickback bandwagon. The framework of regulations which hitherto governed (or had failed to govern) kickbacks and other illicit benefits provided by industry to healthcare professionals was overhauled. The Korea Food and Drug Administration acquired powers to go after givers and takers of kickbacks related to the promotion of drugs, the Ministry of Health and Welfare could now unilaterally reduce, by up to 20%, the reimbursement price of any drug for which kickbacks or other illicit benefits were found to have been provided. For the first time, police and prosecutors acquired express statutory grounds to investigate and prosecute doctors who received benefits intended to influence their drug prescription decisions. Under increasing pressure from all sides to root out corrupt practices, the pharmaceutical industry trade associations undertook to overhaul their voluntary marketing guidelines, to show the world that they were serious about their efforts. The new guidelines were very broad in the scope of activities they covered and draconian in the monetary ceilings they adopted as well as the procedural requirements they imposed on member companies who wish to undertake any of these activities. As a result, these guidelines threaten to burden companies excessively without corresponding benefits in increasing transparency and eliminating corrupt practices, with negative effects on the industry overall.

I. Introduction

For all its modern Western façade, South Korea (hereinafter, “Korea”) remains an Asian country in many ways. Confucian traditions still continue to influence people’s behavior and actions and inform their decision-making. Gift-giving is an integral part of the culture, and business is transacted on the basis of personal relationships. Kickbacks from pharmaceutical companies to healthcare professionals, intended to influence prescription or purchase decisions for drugs, is a problem in almost every nation. However, these characteristics may have made Korea more vulnerable to corrupt practices in the context of interactions between the pharmaceutical industry and healthcare professionals. Structural factors play their part as well – generic prices are said to be set at higher levels than in many other nations, encouraging too many small, inefficient producers to enter the market for a piece of the action, and these players will certainly not be competing on the quality of their products, once they enter.

There have been intermittent government efforts, going back many decades, to curb corruption in the industry, but these were sporadic and small-scale, so things always went back to normal. That is, until the Korea Fair Trade Commission (“KFTC”) launched a systematic investigation into industry practice in October 2006. The scale and scope of this investigation has been unprecedented (the investigation has gone through a number of rounds and is still ongoing) and the penalties imposed on the companies found to have violated the law also unprecedented. The investigation and its aftermath ushered in a new era for the pharmaceutical industry. The regulatory framework governing kickbacks and illicit benefits underwent a major overhaul, thanks to the efforts of other government agencies enthusiastically getting into the action. The public by and large lauded these efforts to root out “black money” that is poisoning the country’s healthcare system and sapping hard-earned taxpayer money funding the national health insurance. “Compliance” became the new watchword for the industry.

Responding to tremendous pressure from all sides, the pharmaceutical industry associations brushed off guidelines they had long ago adopted but which its members had largely

forgotten, and with considerable cajoling from the KFTC, turned them into a very complicated and strict set of rules to be followed in any interaction with healthcare professionals or medical institutions involving economic benefits. These new rules can be expected to have far-reaching consequences for the industry in the years to come, some unintended and many not so positive.

This paper seeks to examine, in turn, the government enforcement activities and rule-making that brought about the dramatic changes in the compliance environment facing pharmaceutical companies in Korea, focusing first on the KFTC, which initiated the changes, and then the health ministry and other regulatory agencies, the industry's response to the changes in the form of new guidelines for interactions with healthcare professionals and medical institutions, and some of the consequences to be expected from the new rules. As we are still in the very early days of the new regulatory regime and the new industry rules, the examination of potential consequences will necessarily be limited.

II. Recent Enforcement Actions in the Korean Pharmaceutical Industry: KFTC

A. Overview

In Korea, the KFTC is the government agency primarily responsible for enforcement of the country's antitrust and fair trade laws – chief among them the Monopoly Regulation and Fair Trade Law (“FTL”). Illicit benefits provided by pharmaceutical companies to healthcare professionals for the purpose of influencing the latter's drug prescription or purchase decisions is a near-universal issue, with which different countries have been grappling various measures and with varying degrees of success. However, Korea seems to be a unique case in that this issue has been tackled on the widest scale and with the farthest-reaching consequences thus far by the country's fair trade authority. The KFTC itself has recognized this, citing its enforcement actions against the pharmaceutical industry as one of the 30 most significant cases it has undertaken in its 30-year history.¹

¹ KFTC News, Korea Fair Trade Commission, *30 Biggest Cases in 30 Years* (April 20, 2011, 13:24 PM), http://ftc.go.kr/news/policy/competeView.jsp?news_no=1035&news_div_cd=1; Tak-Soon Lee, *Pharma Kickbacks Included in KFTC's 30 Greatest Cases*, Dailypharm (April 20, 2011, 12:00 PM),

In October 200, the KFTC launched a series of investigations into promotional activities in the pharmaceutical industry with on-site investigations being conducted of all companies investigated. The purpose of the investigation was to determine whether companies violated the FTL.² A key issue was whether certain practices in the pharmaceutical industry constituted the giving of *excessive* or *improper benefits* to customers intended to induce the customers to do business (e.g., listing on formularies, increasing prescription volumes, etc.) with the giver of those benefits (“unfair business solicitation”), in violation of Article 23.1(iii) of the FTL.

The KFTC found all 17 companies investigated in the first and second rounds in violation of the prohibition against unfair business solicitation, and some liable for other fair trade violations as well.³ The KFTC imposed on the ten companies in the first round (all domestic companies save one, (“Ten Companies”)⁴ corrective orders, administrative fines totaling KRW 19.97 billion (approximately US\$ 17.78 million using current exchange rates) and filed criminal complaints against the top five companies in terms of revenues.

Six of the Ten Companies challenged the legality of the KFTC decisions by filing lawsuits with the appellate court,⁵ contesting both the finding of violations and the basis on which the KFTC computed the fines. Two different divisions within the appellate court

<http://www.dreamdrug.com/Users/News/NewsView.html?ID=140051&keyWord=%B0%F8%C1%A4%B0%C5%B7%A1%C0%A7%BF%F8%C8%B8>.

² The 17 companies investigated were Dong-A, Yuhan, Hanmi, Choongwae, Kukje, Green Cross, Hanall, Ilsung, Samil, Daewoong, Jeil, BMS Korea, Pfizer Pharmaceuticals Korea, GlaxoSmithline Korea, MSD Korea, Lilly Korea, and Otsuka Korea. BMS Korea is the Korean subsidiary of Bristol-Myers Squibb and MSD, the Korean subsidiary of Merck. Press Release, Korea Fair Trade Commission, Corrective Action Against Unfair Customer Solicitation and Resale Price Maintenance, Etc. by 10 Pharmaceutical Companies (Nov. 1, 2007), http://www.ftc.go.kr/news/ftc/reportView.jsp?report_data_no=2819.

³ The first and second rounds were launched at the same time in October 2006, but the KFTC decided the cases for ten companies first in November 2007 (Dong-A, Yuhan, Hanmi, Choongwae, Kukje, Hanall, Ilsung, Samil, Green Cross, and BMS Korea) and for the other seven companies in January 2009 (Pfizer Pharmaceuticals Korea, GlaxoSmithline Korea, MSD Korea, Lilly Korea, Daewoong, Jeil, and Otsuka Korea).

⁴ The types of practices that were found to be illegal in the first round included the giving of cash, gift certificates, and equipment to health professionals, providing entertainment such as through golf or the financing of overseas trips (sometimes with family), payments for post-marketing surveillance studies and clinical observational studies intended to induce prescriptions, and others. Korea Fair Trade Commission, *supra* note 2.

⁵ KFTC decisions may be appealed to the Seoul High Court, which is the appellate-level court, and thereafter, to the Supreme Court, the court of last instance.

reviewed the cases and were split in their decisions. One division confirmed the KFTC's decisions, while the other division essentially confirmed the KFTC's findings as to violations having occurred but overturned the part of the KFTC's decisions as to how broadly the violations were to be viewed as having occurred and how the fines were to be computed.⁶ The Supreme Court in late 2010 remanded the case to the appellate court in those cases where the appellate court had overturned the KFTC's method of computing the fines, in a development widely interpreted as favorable to the KFTC. The Supreme Court decision is examined in greater detail below.

As for the criminal complaints filed against five of the Ten Companies, the Prosecutors' Office subsequently issued summary indictments against all five companies, which two companies accepted.⁷ The three companies that rejected the summary judgments lost in the subsequent criminal proceedings.⁸

With respect to the seven companies in the second round comprising mostly multinational companies ("Seven Companies"), the KFTC found that they violated the FTL by engaging in unfair customer solicitation, resale price maintenance, and/or business interference and as a result, imposed corrective orders and administrative fines amounting to a total of KRW 20.482 billion (about US\$ 18.24 million at current exchange rates) on these companies.⁹ None of the Seven Companies, however, was referred to the prosecutors for investigation into whether

⁶ Myung-Ryong Kim, *Dong-A Pharmaceutical Loses Appeal Against KFTC to Overturn Fines*. Money Today (November 7, 2008, 10:41 AM), <http://www.mt.co.kr/view/mtview.php?type=1&no=2008110710394634283&outlink=1>; Hee-Ra Yoo, *Ilung Follows Yuhan in Winning Partial Victory to Get Fine Overturned*. Medical Today (November 20, 2008, 11:22 AM), <http://www.mdtoday.co.kr/mdtoday/index.html?no=70620>.

⁷ Seok-Hee Hong, *Dong-A Faces Criminal Fine of 150 Million Won, 5 Pharma Companies Summarily Indicted*. Financial News (July 31, 2008, 16:04 PM), http://www.fnnews.com/view?ra=Sent1201m_View&corp=fnnews&arcid=00000921384609&cDateYear=2008&cDateMonth=07&cDateDay=31.

⁸ Jung-Soo Seon, *Criminal Fines Imposed on Pharma Companies for Giving Kickbacks*. KookiNews (July 28, 2009, 17:02 PM), <http://news.kukinews.com/article/view.asp?page=1&gCode=soc&arcid=0921368125&cp=nv>.

⁹ The activities found in violation included (i) the provision of speaker/consultation/advisory service fees, (ii) product presentation meetings, (iii) sponsorship of attendance at domestic and overseas conferences, (iv) provision of supplies and services, (v) PMS studies and (vi) the provision of cash equivalents, where evidence was found that they were intended to induce prescriptions. Korea Fair Trade Commission, *supra* note 2.

their actions constituted criminal violations of the FTL. Some of the Seven Companies are understood to have appealed the KFTC decisions, which appeals are still pending before either the High Court or the Supreme Court.

The KFTC launched yet another round of investigations, this time into six pharmaceutical companies, in March-April of 2009, carrying out on-site investigations of all six and making follow-up requests for documents.¹⁰ The results of this third round are still pending.

B. Legal Basis for KFTC Enforcement

Article 23.1.3 of the FTL prohibits the unfair solicitation of competitors' customers, i.e., the giving of improper or excessive economic benefits to induce purchases from the recipient.

This prohibition is elaborated in the context of promotional practices in the pharmaceutical industry in the voluntary code adopted by the Korean Pharmaceutical Manufacturers Association ("KPMA") and the voluntary code adopted by the Korea Research-Based Pharmaceutical Industry Association ("KRPIA").¹¹ Both were intended as bodies of self-policing guidelines to ensure compliance with Article 23.1.3 of the FTL. Both Codes were adopted pursuant to Article 23.4 of the FTL, which provides that a trade association may voluntarily adopt a code of fair competition for the purpose of preventing unfair customer solicitation. Article 23.5 of the FTL gives the KFTC authority to review and approve such a code for compliance with the FTL, upon request from the trade association. The KFTC has exercised this authority for the initial version of the KPMA/KRPIA Codes as well as their subsequent incarnations.

In a nutshell, the KPMA/KRPIA Codes effectively prohibit drug manufacturers and distributors from giving hospitals or healthcare professionals cash, goods or any other economic

¹⁰ *KFTC 3rd Round Investigation into Pharma Kickbacks*. Yonhap News (March 31, 2009, 11:11 AM), <http://news.naver.com/main/read.nhn?mode=LSD&mid=sec&sid1=101&oid=001&aid=0002581494>.

¹¹ The Codes will hereinafter be referred to as the "KPMA Code" and the "KRPIA Code," respectively, and the "KPMA/KRPIA Codes," collectively.

benefits in connection with the sale of pharmaceutical drugs, unless they are explicitly permitted under the KPMA/KRPIA Codes and are within the bounds of normal commercial practice. The KPMA/KRPIA Codes are examined in greater detail below in a separate section.

C. KFTC Findings

1. Generally

(i) *Emphasis on promotional activity's relevance to prescription*

In the previous rounds of investigations, the KFTC tended to interpret what is considered “unfair customer solicitation” quite broadly. If the KFTC found evidence that showed a certain benefit provided to a hospital or healthcare professional through a promotional activity was “relevant to prescriptions,” i.e., intended to influence the purchase or prescription decisions of the recipient hospital or healthcare professional, the KFTC presumed that such benefit was improper and/or excessive and hence in violation of the FTL. Therefore, any activity that provides benefits to hospitals or healthcare professionals may potentially be deemed to constitute unfair customer solicitation, where there is evidence to link that activity to the purchase or prescription decisions for drug(s) being marketed by the pharmaceutical company engaging in such activity.

(ii) *Significance of compliance with the KPMA/KRPIA Codes*

Both the KPMA and KRPIA Codes are standards voluntarily adopted by industry associations and, as such, do not have the status of law. Consequently, a violation of the KPMA or KRPIA Code is not automatically deemed as a violation of the law. The KFTC has nevertheless tended to presume the illegality of promotional activities which are conducted outside the limits provided for in the KPMA/KRPIA Codes or activities which are not provided for in the KPMA/KRPIA Codes at all, and the burden shifted to the pharmaceutical company engaging in

such activities to rebut the presumption. If the company fails to offer an acceptable rebuttal, then the presumption will remain, from a practical perspective.

It should also be noted that compliance with the monetary limits provided for in the KPMA/KRPIA Codes does not provide an absolute safe harbor for pharmaceutical companies. In other words, even where a company has adhered to the monetary limits provided for in the KPMA/KRPIA Codes (e.g., KRW 50,000 per person limit on meals for healthcare professionals attending product presentation meetings hosted by the company), if the KFTC found evidence that the activity was intended to influence drug purchase/prescription decisions, the KFTC deemed such activity to be a violation of the FTL.¹²

(iii) “Single Comprehensive Violation” based on a company’s marketing plan or a pattern of repetition consisting of benefits provided

Where the KFTC found what it considers to be evidence of the company’s intent to provide benefits to healthcare professionals/hospitals to influence drug purchase/prescription decisions (such evidence has consisted mostly of marketing plans, whether prepared at a company-wide level or limited to specific business units or branches) and of the company’s implementation of such intent in the form of various promotional activities through which benefits were provided to healthcare professionals/hospitals (such evidence has mostly taken the form of daily call reports submitted by sales reps or proposals and approval documents for promotional expenditures), the KFTC deemed all such activities as a “single comprehensive violation” that spans the entire period in which the relevant types of promotional activities have been carried out.¹³ Even in cases where the KFTC found evidence that links only a handful of instances of any given type of

¹² Korea Fair Trade Commission, *supra* note 2; Press Release, Korea Fair Trade Commission, Corrective Action Against Unfair Customer Solicitation and Resale Price Maintenance, Etc. by 7 Pharmaceutical Companies (Jan. 15, 2009) (on file with author).

¹³ Korea Fair Trade Commission Decision, rendered May 12, 2009, Case No. 2007Kyungkyu1858 (available on KFTC website <http://ftc.go.kr/laws/book/judgeSearch.jsp>).

promotional activity to an intent to improperly influence drug purchase/prescription decisions, the KFTC has tended to view such evidence as sufficient to deem illegal all instances of the promotional activity in question conducted during the period for which marketing plans have been found, based on the general indications in such plans to use the type of activity in question to influence drug purchase/prescription decisions.

2. By Type of Activity

The KFTC seems to be of the position that certain activities such as golf, provision of cash (and cash equivalents, such as gift certificates), and entertainment (especially with excessive alcohol) should be deemed straightforward violations for which the KFTC will take a bright-line approach without considering any mitigating factors. For promotional activities which are permitted subject to certain restrictions under the KPMA/KRPIA Codes, the KFTC has determined such activities to be illegal where it has found evidence to suggest that the activity was intended to influence the drug purchase/prescription decisions of the recipient healthcare professionals/hospitals.

a. Provision of Gift Certificates, Cash and Payment for Golf, & Entertainment at Improper/Adult Venues

The KFTC's position appears to be that all activities in this category should be deemed straightforward violations, and as such, illegal without exception. For instance, the KFTC has stated with respect to golf that payment for golf cannot be justified as being part of social custom, since the pharmaceutical company provides it as a quid pro quo for the prescription of its products.¹⁴

¹⁴ Korea Fair Trade Commission Decision, rendered December 20, 2007, Case No. 2007Kyungkyu1865

b. Provision of Medical Journals and Equipment

The KPMA/KRPIA Codes in effect at the time of the KFTC's decisions on the first and second round investigations imposed a limit of KRW 300,000 per year for provision of medical journals and equipment for research purposes. The KRPIA Code further limits this by providing that the KRW 300,000 per year ceiling applies on a per hospital department/clinic (i.e., not individual healthcare professional) basis. The KFTC appears to have found violations where the provision of medical journals and equipment was in excess of the guideline set by the KPMA/KRPIA Codes. The KFTC's stated position on this issue in a case in point is that "it is natural in light of social conventions that a medical institute should procure equipment, etc. at its own expense, and the purpose for the provision of equipment [by the pharmaceutical company] was to maintain and/or increase the prescription by providing economic benefits to hospitals, clinics and their physicians."¹⁵

c. Sponsorship for Individual Healthcare Professional Attendance at Domestic/Overseas Conferences

Under the KPMA/KRPIA Codes in effect at the time of the KFTC's decisions on the first and second round investigations, a pharmaceutical company was permitted to sponsor a healthcare professional to attend a domestic/overseas academic conference, provided that (i) the healthcare professional is a speaker, presenter, moderator or panelist, (ii) the scope of sponsorship is limited to airfare (economy class), transportation from the airport to the hotel and back, registration fees, meals and accommodations, and (iii) the sponsorship is provided to a publicly recognized academic society or research institution and not paid directly to the individual

(available on KFTC website <http://ftc.go.kr/laws/book/judgeSearch.jsp>).

¹⁵ Korea Fair Trade Commission Decision, rendered December 20, 2007, Case No. 2007Kyungkyu1861 (available on KFTC website <http://ftc.go.kr/laws/book/judgeSearch.jsp>).

healthcare professionals who are being sponsored. The KFTC found sponsorships which do not meet the above criteria to be in violation of the FTL. In particular, payments for family members to accompany healthcare professionals or for healthcare professionals to engage in golf outings, tours and other forms of recreational activities as part of sponsoring conference attendance were found illegal.¹⁶

d. Financial Donations

The KPMA/KRPIA Codes in effect at the time of the KFTC's decisions on the first and second round investigations only permitted financial donations to publicly recognized academic societies or research institutions (e.g., those approved by the Ministry for Health and Welfare or recognized by the Korea Medical Association, Korea Dental Association, etc.). In other words, financial donations to hospitals and other medical institutions were not among the types of benefits permitted under the KPMA/KRPIA Codes. In line with this principle, the KFTC applied a heightened level of scrutiny to donations made directly to hospitals or universities/medical schools that are affiliated with certain hospitals. Against the general guiding principle stated above, the KFTC tended to make the determination of illegality on donations on a case-by-case basis, taking into account the totality of circumstances including the existence of any evidence indicating that the donation was made with the intent to influence drug purchase decisions of the recipient.¹⁷

e. Speaker Fees/Advisory or Consulting Service Fees

The KRPIA Code was amended in 2007 to provide for a KRW 500,000

¹⁶ Korea Fair Trade Commission Decision, rendered December 20, 2007, Case No. 2007Kyungkyu1867 (available on KFTC website <http://ftc.go.kr/laws/book/judgeSearch.jsp>).

¹⁷ Korea Fair Trade Commission Decision, rendered December 20, 2007, Case No. 2007Kyungkyu1862 (available on KFTC website <http://ftc.go.kr/laws/book/judgeSearch.jsp>); Korea Fair Trade Commission Decision, rendered December 20, 2007, Case No. 2007Kyungkyu1872 (available on KFTC website <http://ftc.go.kr/laws/book/judgeSearch.jsp>).

ceiling on honoraria payments to healthcare professionals for lectures up to one hour in length. The KPMA Code, on the other hand, was silent on the issue of honoraria payments.¹⁸ The above amendment to the KRPIA Code was not reviewed or approved by the KFTC. As such, while the KRW 500,000 ceiling may have been considered by the KFTC as one of the factors in determining what constitutes reasonable and fair market value, keeping payments to under KRW 500,000 did not guarantee that such payments would be viewed as lawful.

The KFTC has been particularly sensitive to internal documents found in multinational pharmaceutical companies which indicate that the companies segment healthcare professionals into different groups or grades according to perceived importance in terms of influence on purchase/prescription decisions regarding the company's products and "manage" the different grades of healthcare professionals using different promotional tools, such as the payment of speaker fees or advisory/consulting service fees.¹⁹ The KFTC also appears to have taken into consideration the frequency of speaker or advisory/consulting engagements entered into by the company and the total amount of fees expended for such engagements in determining the legality of such fee payments.²⁰

f. Educational Meetings Hosted by Companies for Healthcare Professionals

For product presentation meetings, symposia or lectures organized by pharmaceutical companies for healthcare professionals, the organizing company was permitted under the KPMA/KRPIA Codes in effect at the time of the KFTC's decisions on the first and second round investigations to provide

¹⁸ The current versions of the KPMA/KRPIA Codes do not contain any provisions on speaker fees or consulting fees.

¹⁹ Korea Fair Trade Commission, *supra* note 12.

²⁰ *Id.*

meals/beverages and/or souvenirs, each not exceeding KRW 50,000 per person, and support costs for domestic travel and accommodations for attending healthcare professionals by reimbursing actual expenses incurred. The KFTC tended to view such meetings as being prone to abuse by pharmaceutical companies which use them as a pretext for the actual purpose of providing meals and entertainment to healthcare professionals to influence their prescriptions. Accordingly, where the KFTC found evidence indicating that the meeting in question was held with the primary intent to provide benefits to healthcare professionals in the form of meals rather than providing valuable scientific information on the company's products/related diseases, the KFTC found such meetings to be illegal, even in cases where the KRW 50,000 per person limit was adhered to.²¹

g. Post-Marketing Surveillance

The KFTC has applied a particularly strict standard to post-marketing surveillance studies conducted by pharmaceutical companies, based on the assumption (widely shared within the industry) that such studies are often used as a pretext for the companies to provide cash payments to participating healthcare professionals in the form of service fees, as opposed to being indispensable tools for the collection of valuable data on the safety and/or efficacy of drugs post-launch. Even in the case of post-marketing surveillance studies mandated under applicable laws, the KFTC has held that companies which conducted studies involving significantly more cases than the minimum number of cases required under the law (3,000 or 600, depending on the type of drug) or which conducted studies with the intent to induce or reward prescriptions of the product in question were in violation of the FTL.²²

²¹ Korea Fair Trade Commission, *supra* note 16.

²² Korea Fair Trade Commission, *supra* note 13.

Regarding voluntary post-marketing surveillance, i.e., post-marketing surveillance of drugs which are not required under applicable laws, the KFTC looked to the following factors to determine the legality of payments to healthcare professionals: the number of cases contracted with individual healthcare professionals, the amount of payment per case (KRW 50,000 per case prescribed under the KPMA/KRPIA Codes in effect at the time was taken as a general rule of thumb, but the KFTC found a number of PMS studies to be illegal even where the above monetary limit was adhered to, based on its review of other factors), whether a convincing scientific rationale existed for the study, the quantity and quality of the data collected (e.g., in case report forms) and how well the company had utilized such data, in addition to any indications that the study was intended to induce or reward prescriptions of the product in question.²³

h. Samples

The KPMA/KRPIA Codes in effect at the time of the first two rounds of investigations permitted the giving of free product samples to healthcare professionals/hospitals only under very stringent conditions -- in principle, samples are permitted only in a minimum packaging unit per healthcare professional on one occasion only throughout the entire lifecycle of the product. It appears that the KFTC adopted a similarly stringent standard in reviewing the legality of providing samples.²⁴

D. KFTC Sanctions

1. General

If a company is found to have violated the FTL with respect to any of its

²³ *Id.*

²⁴ Korea Fair Trade Commission, *supra* note 2.

promotional activities, the KFTC may impose (i) a corrective order, (ii) public announcement of the violation in the daily newspapers and/or (iii) administrative fines in the amount of 0.1 ~ 1.0% of the relevant revenues. In addition to the above, the KFTC may refer the company to the prosecutor's office for further investigation. If indicted by the prosecutor and found guilty by the courts, sanctions may be up to 2 years of imprisonment or up to KRW 150 million in criminal fines (the prison term would apply only to natural persons, i.e., the responsible managers; the fine may apply to both the company and the responsible managers).

2. Administrative Fine

For the companies found in violation of the FTL in the first and second rounds of investigations, the KFTC determined the administrative fine amount by applying a pre-established penalty rate to the "relevant revenue amount" for each product regarding which and for the relevant period during which the activities found to be in violation of the FTL had occurred.

a. Relevant Period

During the first and second round of investigations, the KFTC considered the "relevant period" to be the entire period from the date on which the first violation was found for that product until the end date of the period subject to the KFTC's investigation (i.e., September 30, 2006 in the first and second rounds). The KFTC's position is based on the assumption that the repeated benefits provided through the different activities constitute a single comprehensive violation, the effect of which lasted up to the end date of the period under investigation.

b. Relevant Revenues

In previous investigations, the KFTC considered the total revenues

earned during the “relevant period” for each of the products for which activities had been found to be in violation of the FTL as the “relevant revenues” for the purpose of calculating the amount of the fine. This computation method was contested in the courts and the Supreme Court ultimately took a position favorable to the KFTC, as discussed above and again below.

c. Administrative Fine Rate

The amount of administrative fine is calculated by multiplying a pre-established rate of administrative fine ranging from 0.1% to 1.0% to the “relevant revenues.” The actual rate to be imposed will depend on the “seriousness” of the violation as determined by the KFTC. The range of applicable rates is as follows:

Seriousness of the Violation	Standard Administrative Fine Rate
Very serious	0.8~1.0 %
Serious	0.4~0.8 %
Less serious	0.1~0.4 %

During the first and second rounds of investigations, the KFTC uniformly imposed administrative penalties at the rate of 1.0% on all companies investigated, based on the following factors provided for in its internal guidelines: (i) The violation caused or is highly likely to cause severe damage to consumers; (ii) Investigated companies have 3-year average revenues of 50 billion KRW or more; and (iii) The violations have occurred throughout the nation-wide market and therefore should be considered “very serious violations.”²⁵

E. Court Decisions

²⁵ Korea Fair Trade Commission Guidelines for Criminal Referrals of Violations of the Monopoly Regulation and Fair Trade Law, KFTC Guideline No. 40 (January 15, 2007).

As we noted above, certain pharmaceutical companies subject to the first and second rounds of the investigations appealed the KFTC's decision. On the whole, the appellate court, regardless of which division heard the case, tended to side with the KFTC on the issue of violation of law, recognizing and accepting the KFTC's standard for determining illegality. However, the two divisions which reviewed the cases took different approaches to the issue of whether a number of different types of promotional activities should be deemed a "single comprehensive violation" based on a handful of instances for which evidence was found linking the benefits provided through such activities to an intent to improperly influence prescriptions. As discussed above, whether to recognizing a "single comprehensive violation" can make a huge difference in the amount of the fine, and by extension, impact the likelihood of the company being referred to the prosecutor's office for a criminal investigation as well as being notified to other relevant government agencies for further investigation.

In the case of Hanmi's appeal, the Seoul High Court reduced the initial penalty amount levied by the KFTC from KRW 5.098 billion to KRW 1.52 billion (approximately US\$ 4.54 million to US\$ 1.35 million using current exchange rate) based on grounds that the KFTC had incorrectly calculated the administrative fine amount. The High Court ruled that the administrative fine should be calculated based on the sales related only to the specific unfair solicitation activity (e.g., the sale amount generated from providing excessive or improper payments for a lecture) for which the KFTC provided sufficient evidence, and it was improper to include all sales amounts generated from a product simply based on only a select few violations.²⁶

However, the Supreme Court rejected the reasoning of the Seoul High Court and held that it is proper to consider all sales amounts generated by a product as relevant revenues for purposes of calculating the fine, if the activities were used to implement an overall sales plan (e.g., plans of action commonly referred to as POAs) established by the company for customers in general.²⁷ In other words, the total sales amounts generated by selling a relevant product to

²⁶ Seoul High Court Decision, rendered May 14, 2009, Case No. 2008Nu2530 (available at Korean Supreme Court website <http://glaw.scourt.go.kr/jbsonw/jsp/jbsonc/jbsonc08.jsp>) .

²⁷ Supreme Court Decision, rendered November 25, 2010, Case No. 2009Du9543 (available at Korean Supreme Court website <http://glaw.scourt.go.kr/jbsonw/jsp/jbsonc/jbsonc08.jsp>).

all customers should be considered as relevant revenues, if the marketing or promotional activity in question was part of the implementation of a general sales plan.

In sum, with respect to the method of calculating the administrative fine amount, the Supreme Court found that when the marketing activities for a particular product are based on a plan and are carried out as part of the implementation of such plan, the appropriate method of calculating the administrative fine amount is to use the total revenues generated from the sale of that product to all channels and accounts. This ruling appears to be based on the assumption that the authorities would face an unduly heavy burden if required to prove that for each activity, out of the many thousands conducted by the company in question, excessive or improper benefits were provided for promotional purposes.

III. Other Agency Involvement

Other interested government agencies were not slow to follow the KFTC's lead and jump on the anti-kickback bandwagon. The result was a major overhaul of the country's laws and regulations governing the marketing and sale of pharmaceuticals, with the objective of rooting out illicit benefits intended to influence healthcare professionals. These legislative and regulatory developments are discussed below.

A. Korea Food & Drug Administration

In December 2008, the Ministry of Health and Welfare revised applicable regulations to impose both criminal and administrative sanctions against pharmaceutical companies which provided kickbacks to healthcare professionals. Previously, the Enforcement Regulation to the Pharmaceutical Affairs Law had contained the only prohibition on kickbacks specific to the pharmaceutical industry. The relevant provision, which was one of a number of provisions listing the obligations of those engaged in the sale of pharmaceuticals, had prohibited "product registration holders, importers, and wholesalers of pharmaceuticals" from providing "operators of

medical institutions or pharmacies” with “prizes, free gifts, and other giveaways for the purpose of promoting the sale of pharmaceuticals.”²⁸ As an enforcement tool against kickbacks, this provision contained serious deficiencies in its language – most problematically, the prohibition only on “prizes, free gifts, and other giveaways” and the limitation of recipients to “operators of medical institutions or pharmacies,” which left out individual healthcare professionals. Due to the combined effect of such deficiencies and a lack of will on the part of the agency responsible for enforcing the regulation, the Korea Food and Drug Administration (“KFDA”), this provision had never been enforced against pharmaceutical companies for providing illicit benefits to healthcare professionals or hospitals.

After the 2008 amendments, the provision read as follows: “Product registration holders, importers, and wholesalers of pharmaceuticals shall not provide healthcare professionals, or operators of medical institutions or pharmacies with money, goods, conveniences, labor, entertainment, or any other economic benefits for the purpose of promoting the sale of pharmaceuticals.”²⁹ Violations would be subject to varying degrees of administrative sanctions, depending on the frequency of the violation: 1-month, 3-month, 6-month suspension of sale of the relevant product for first-time, second-time, and third-time violations, respectively, and cancellation of the relevant product registration for fourth-time violations.³⁰ Under the amended provision, the KFDA could now impose sanctions on pharmaceutical companies for providing illicit benefits, regardless of form or substance, to individual healthcare professionals.

Despite being granted this new enforcement tool against kickbacks, the KFDA lacked the institutional expertise and experience to vigorously pursue violators, not to mention search and seizure powers necessary for the effective investigation of alleged kickbacks. It was not until the Central Investigations Unit (“CIU”) was formed within the KFDA in February 2009 that the amended regulation started to have bite. The CIU began as a temporary task force, headed

²⁸ Enforcement Regulation to the Pharmaceutical Affairs Law, Article 62(1)-5.

²⁹ Enforcement Regulation to the Pharmaceutical Affairs Law, Article 62(1)-5, as revised by Ministry of Health, Welfare, and Family Affairs Order No. 77, dated December 1, 2008.

³⁰ Addendum 8 to the Enforcement Regulation to the Pharmaceutical Affairs Law, II. 35(h).

by a prosecutor seconded from the Seoul Central District Public Prosecutor's Office and staffed with KFDA investigative personnel, but formally became a part of the KFDA in April 2009.³¹ It was modeled after the Office of Criminal Investigations within the U.S. Food and Drug Administration and has jurisdiction to investigate violations of the Pharmaceutical Affairs Law and the Food Sanitation Law, two main statutes for which the KFDA has enforcement authority.³² The CIU is responsible for conducting and coordinating criminal investigations into a broad spectrum of crimes relating to food and drugs and was not formed with a specific mandate to focus on pharmaceutical industry kickbacks to healthcare professionals. However, driven by the government's firm determination to root out longstanding illicit practices in the healthcare sector and broad-based public for such efforts, the CIU has emerged during its relatively short existence as a significant force in uncovering kickback schemes, resulting in penalties for the relevant companies under the amended regulation.³³

B. Ministry of Health & Welfare

In January 2009, the Ministry of Health and Welfare³⁴ amended reimbursement pricing

³¹ Joo-Ho Park, *Safety of Food and Drugs Should Meet Consumer Expectations*. Kookmin Ilbo, Kooki News (December 22, 2009, 10:07 AM), <http://news.kukinews.com/article/view.asp?page=1&gCode=kmi&arcid=1261476336&cp=nv>.

³² *Id.* However, unlike its American counterpart, the CIU does not have jurisdiction to investigate violations of laws governing medical devices and cosmetics, two other sectors over which the KFDA has jurisdiction.

³³ Se-Ho Lim, *CIU First Anniversary of Launch, Total 669 Food and Drug Law Violators Rounded Up in First Year of Operation*. Yakup Shinmun (May 17, 2010, 14:25 PM), <http://www.yakup.com/news/index.html?mode=view&cat=11&nid=130994>; Seung-Hyun Chun, *Youngjin Pharmaceuticals Found to Have Given Kickbacks, Chooses to Pay KRW 50 Million in Administrative Fine*. EDaily (March 19, 2010, 08:14 AM), <http://www.edaily.co.kr/news/NewsRead.edy?SCD=DC14&newsid=01312006592904960&DCD=A00204&OutLnkChk=Y>; Myung-Ryong Kim, *Prosecutor's Office, Police, KFTC Close in from All Sides on Pharma Company Kickbacks*. Money Today (April 4, 2011, 17:05 PM), <http://www.mt.co.kr/view/mtview.php?type=1&no=2011040415503299207&outlink=1>.

³⁴ The Korean health ministry was previously named Ministry of Health, Welfare, and Family Affairs, before its name was changed to Ministry of Health and Welfare, effective March 19, 2011, as part of an administrative reshuffling of various ministry functions. <http://news.hankooki.com/lpage/politics/201003/h2010030916325421000.htm>

rules for drugs covered by the National Health Insurance Program, effective August 1, 2009, to include “interference with the orderly distribution of drugs by such means as providing money or other valuables to promote sales” as one of the grounds on which the Ministry could reduce the maximum reimbursement price of a drug.³⁵ Under a separate attendant regulation issued by the Ministry, the rate of price reduction is to be calculated by dividing the Korean Won amount of kickbacks or other illicit benefits provided to the recipient medical institution by the Korean Won amount of the prescriptions written for (or the purchases made of) the relevant product(s) by the recipient, with the rate not to exceed 20% of the current reimbursement price.³⁶

This new rule, dubbed the “kickback-drug price linkage,” has been widely criticized as being unworkable in practice despite its laudable objective, primarily in light of the potential overkill factor (a single instance of a small kickback to a physician can result in a catastrophic price reduction of the company’s bestselling product) and the difficulty of identifying the product(s) for which kickbacks or illicit benefits were provided (kickbacks are often provided, particularly when the recipients are hospitals, with a view to inducing or rewarding prescriptions for a company’s line-up of products across the board, rather than for a single product).³⁷ However, it is reasonable to expect that the deterrent effect of this rule would be significant, particularly since it has the potential to hit pharmaceutical companies where they would feel the most hurt, i.e., their bottom lines.

The basic assumption on which the Ministry has adopted this “linkage” is that the National Health Insurance Program should not be funding pharmaceutical companies’ kickbacks by sustaining drug reimbursement prices at unwarrantedly high levels and this assumption seems to be shared by the current Administration of President Myung-Bak Lee and the majority of the public.³⁸ In announcing the adoption of this new rule, the Ministry stated that it would

³⁵ Regulation on Standards for National Health Insurance Reimbursement (Ministry of Health and Welfare Enforcement Regulation), Article 13.11.

³⁶ Standards for Price Reduction of Drugs Interfering with Orderly Distribution (Ministry of Health and Welfare Notification).

³⁷ Eun-Taek Choi, *20% Reduction to be Expected for Drugs Found to Have Been Tied to Kickbacks*, Dailypharm (April 15, 2011, 12:30 PM), <http://www.dreamdrug.com/Users/News/NewsView.html?ID=139863>.

³⁸ Press Release Ministry of Health, Welfare, and Family Affairs, (July 30, 2009) (on file with author).

strengthen its system for monitoring the marketing and sale of drugs and also establish a close-knit network of cooperation with the police/public prosecutor's office and the KFTC, which would enable the Ministry to utilize the results of investigations undertaken by these agencies in the application of the new drug pricing rule.³⁹ The expectation in applying the new rule, according to the Ministry, is that it would help bring about greater transparency in drug sales, thereby enabling the funds used for kickbacks to be channeled into R&D and quality improvement, resulting in greater competitiveness of the Korean pharmaceutical industry as a whole and reducing the burden of drug costs on taxpayers.⁴⁰ The new rule has yet to be applied in practice, but in light of the above factors, it can reasonably be assumed that the "linkage" is here to stay and will soon find targets.

C. Police/Public Prosecutors' Office

Providing kickbacks or other illegal benefits provided to healthcare professionals for the purpose of inducing or rewarding prescriptions or sales can constitute official bribery, in cases where the recipient is an employee of a government hospital, or commercial bribery, where the recipient is an employee of a privately-owned hospital, both punishable offenses under the Korean Criminal Code.⁴¹ Both the giver and the recipient are subject to punishment under the relevant provisions.⁴²

These tools have always been available to Korea's police and prosecutors, but in recent years, particularly after the start of KFTC investigations and enforcement actions, the police and the public prosecutors' office have also stepped up efforts to investigate and prosecute individuals alleged to have given or received bribes in the context of interactions between pharmaceutical companies and healthcare professionals.⁴³ Indictments appear to have been

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ Criminal Code, Articles 129(1), 357(2).

⁴² Criminal Code, Article 133(1), 357(2).

⁴³ Eun-Taek Choi, *Prosecutors' Office or KFTC? Confusing...* Dailypharm (April 8, 2011, 06:49 AM),

considerably fewer, though, than the reported instances of investigations undertaken suggest, and fewer still of such indictments have been sustained by the courts. This can likely be attributed to the far more stringent elements of the violations under the Criminal Code and the standards of proof required in criminal cases. A notable exception is the recent “contrast media case,” where the Seoul District Police, acting on the tip of a whistleblower, investigated 355 physicians on allegations of receiving kickbacks from four contrast media companies (three multinational, one domestic) in the form of services fee payments for sham post-marketing surveillance studies.⁴⁴ Of the physicians investigated, the prosecutor eventually issued indictments against 3 physicians, in addition to 6 executives of the relevant companies, and suspended indictments against 41 of the doctors, taking mitigating factors (e.g., small amount received) into account.⁴⁵

Efforts by the police and prosecutors have appear to have gained renewed steam in recent months with the adoption of the “Dual Punishment System,” discussed below.

D. Adoption of “Dual Punishment System”

In November 2010, the so-called “Dual Punishment System” was adopted to impose criminal sanctions not only on givers but also on recipients of illicit benefits. In addition to the provision in the Enforcement Regulation to the Pharmaceutical Affairs Act, which was amended in 2008 to enable enforcement against pharmaceutical companies for providing kickbacks to individual healthcare professionals (discussed above), a new provision was inserted to allow enforcement against the recipients, i.e., “pharmacists and oriental medicine pharmacists” who

<http://www.dreamdrug.com/Users/News/NewsView.html?ID=139475>; Byung-Ki Min, *High Intensity Probe Into Kickbacks: Three Types of Responses from Industry*. Munhwa.com (April 6, 2011, 14:09 PM), <http://www.munhwa.com/news/view.html?no=2011040601031524237004>.

⁴⁴ Do-Kyung Lee, 355 “Kickback Doctors” Uncovered; They Received Cash, Golf Outings, and Even Got Expenses Paid for Mother-In-Law’s 60th Birthday. Kooki News (February 26, 2008, 19:04 PM), <http://news.kukinews.com/article/view.asp?page=1&gCode=kmi&arcid=0920823516&cp=nv>; Dong-Keun Lee, *Contrast Media Kickback Taking Doctors, 41 Get Their Licenses Suspended*. Health Korea News (March 2, 2009, 18:16 PM), <http://www.hkn24.com/news/articleView.html?idxno=23407>.

⁴⁵ *Id.*

received such kickbacks.⁴⁶ A corresponding provision was inserted into the Medical Services Law, to enable enforcement against “healthcare professionals, operators of medical institutions, and employees of medical institutions” who received kickbacks from pharmaceutical companies.⁴⁷ Recipients may be punished by imprisonment of up to 2 years or a criminal fine of up to KRW 30 million, along with confiscation of the benefits received.⁴⁸ These amendments represented a sea change to the relevant laws, which for the first time provided expressly for criminal sanctions against healthcare professionals for receiving kickbacks from industry.

IV. Revised Industry Codes

A. Overview – KPMA and KRPIA

The Korea Pharmaceutical Manufacturers’ Association (“KPMA”) and the Korea Research-Based Pharmaceutical Industry Association (“KRPIA”) are the two pharmaceutical industry trade associations in Korea. The KPMA mainly comprises domestic pharmaceutical companies, while the KRPIA exclusively comprises multinational pharmaceutical companies.

The KPMA Code was first adopted in 1994 and amended in 2001, mainly in response to calls from member companies to raise the monetary ceilings for meals provided to healthcare professionals. The KPMA Code underwent a major overhaul in 2009, when the KPMA leadership sought to incorporate new, far-reaching restrictions on the entire spectrum of promotional activities, in order to placate the KFTC after its recent aggressive enforcement efforts and to address the broad-based criticism of industry practices that the KFTC’s findings had engendered in the public. Behind-the-scenes discussions between the KPMA leadership and the KFTC and much wrangling among the member companies produced another round of amendments in 2010, resulting in the version that is currently in effect. All incarnations of the

⁴⁶ Pharmaceutical Affairs Law, Article 47(3).

⁴⁷ Medical Services Law, Article 23-2.

⁴⁸ Medical Services Law, Article 88-2, Pharmaceutical Affairs Law, Article 94-2.

KPMA Code have been reviewed and approved by the KFTC, the latest version having been approved on December 17, 2010 and become effective on December 20, 2010.

The KRPIA was formed much later than the KPMA and the KRPIA Code was first adopted in 2006. The KRPIA Code, too, underwent similar revisions in the aftermath of the KFTC's enforcement actions. The current version, which differs slightly from the KPMA Code, reflecting the different market conditions for and the resulting difference in focus of the multinational companies' marketing efforts, was adopted in January 2011 and approved by the KFTC on January 11, 2011.

B. Basic Principles

The KPMA/KRPIA Codes set forth the basic principles that govern pharmaceutical marketing activities: (i) such activities should be conducted within the bounds of applicable laws, including the FTL, and socially accepted commercial practice; (ii) Companies should endeavor to deliver to healthcare professionals scientific and educational information on products and maximize benefits to patients, provided that such endeavors should not interfere with the independent decision-making of healthcare professionals regarding the prescription of drugs; (iii) marketing activities should take place at venues appropriate to the purpose of such activities; and (iv) book-keeping and other financial management should be based on applicable laws and generally accepted accounting principles, be factually accurate and transparent.⁴⁹

This is broadly comparable to the principles set forth in the Preamble and beginning sections of the PhRMA Code, which emphasize that companies' interactions with healthcare professionals should benefit patients and enhance the practice of medicine⁵⁰ and that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical

⁴⁹ KPMA Code Art. 2, KRPIA Code Art. 2.

⁵⁰ PhRMA Code on Interactions with Healthcare Professionals 2, 4 (2009).

knowledge and experience.⁵¹ The emphasis on accurate and transparent book-keeping in the KPMA/KRPIA Codes is intended to address the widespread concern shared by Korean authorities that companies have engaged in accounting irregularities and doctoring their books to hide expenses incurred for illicit promotional activities.⁵²

C. Definitions

The KPMA/KRPIA Codes contain a separate section on definitions of terms used, the most significant of which are outlined below:⁵³

- “Drugs” are (i) prescription drugs and (ii) over-the-counter (“OTC”) drugs which are reimbursable under the National Health Insurance Plan (“NHIP”), both as defined under the Pharmaceutical Affairs Act.⁵⁴ Accordingly, promotional activities relating to OTC drugs which are not reimbursable under the NHIP are technically not covered by the KPMA/KRPIA Codes. It is unclear why the definition leaves out a broad category of drugs, many of which are not reimbursable under NHIP, but this definition has remained the same in all incarnations of the KPMA/KRPIA Codes. It may reflect the assumption on the part of the initial drafters that only prescription drugs, because the requirement of a physician’s prescription created an agency problem, and reimbursable OTC drugs, because their purchases were being funded at least in part by taxpayer money, through the NHIP, should be subject to the regulation of promotional activities. While the language does seem to suggest a potential loophole, it does not seem likely that the KFTC or any other enforcement agency would be willing to let companies exploit this

⁵¹ PhRMA Code on Interactions with Healthcare Professionals 2 (2009); Howard L. Dorfman, *The 2009 revision to the PhRMA Code on Interactions with Healthcare Professionals: Challenges and Opportunities for the Pharmaceutical Industry in the Age of Compliance*, 31 Campbell L. Rev. 361, 361-362 (2008-2009).

⁵² Press Release, Korea Fair Trade Commission, Standard Fair Competition Code Adopted for Pharmaceutical Industry (Dec. 24, 2009) (on file with author).

⁵³ The terms whose definitions discussed below are capitalized hereinafter, in discussing the relevant provisions of the KPMA/KRPIA Codes.

⁵⁴ KPMA Code, Art. 3(1), KRPIA Code, Art. 3(1).

and argue for a more lenient standard to be applied to promotional activities for non-reimbursable OTC drugs, only based on the definition contained in the KPMA/KRPIA Codes. The KFTC seems to be taking the view that no distinction is warranted between reimbursable and non-reimbursable OTC drugs, with respect to the enforcement of the FTL.⁵⁵

- “Company/Companies” refers to any entity in the business of manufacturing and selling or importing and selling drugs after having obtained the requisite licenses.⁵⁶
- “Healthcare Professionals” are doctors, dentists, oriental medicine doctors, pharmacists, and oriental medicine pharmacists.⁵⁷ Nurses are not included in the scope of Healthcare Professionals.
- “Donation” refers to any act by a Company of providing Money or Other Valuables,⁵⁸ without consideration, to medical institutions, schools, or agencies/organizations which conduct academic or other research or engage in academia-industry cooperative efforts (hereinafter, collectively “Medical Institutions”).⁵⁹
- “Academic Conference” is any event held for the purpose of supporting medical or pharmaceutical research and education of Healthcare Professionals by providing Healthcare Professionals with medicine/pharmacy-related scientific or educational information, excluding any event which is in substance hosted by a Company.⁶⁰ Among Academic Conferences, a “Domestically-held International Academic Conference” is an academic conference of an international scale held in Korea, for two (2) or more days, attended by Healthcare Professionals from five (5) or more countries

⁵⁵ Q&A Session with Jin-Wook Chung, Division Head, Anti-Monopoly Division (Manufacturing), Anti-Monopoly Bureau, KFTC, at Information Session on the Amended KPMA Code (March 31, 2010).

⁵⁶ KPMA Code, Art. 3(2), KRPIA Code, Art. 3(2).

⁵⁷ KPMA Code, Art. 3(5), KRPIA Code, Art. 3(5).

⁵⁸ As defined below, in KPMA Code, Art. 3(12), KRPIA Code, Art. 3(12).

⁵⁹ KPMA Code, Art. 3(7), KRPIA Code, Art. 3(7).

⁶⁰ KPMA Code, Art. 3(8), KRPIA Code, Art. 3(8).

(Healthcare Professionals from five (5) or more countries attending as audience, not as presenter, chair or panelist, must come to Korea) or by participants of whom 150 or more are foreigners, and recognized by a medical doctors' association, dentists' association, or oriental medical doctors' association, defined under the Medical Services Law, or by the Korean Pharmaceutical Association or the Korea Oriental Pharmacy Association, defined under the Pharmaceutical Affairs Law, as an international academic conference. "International Academy" is an academy recognized by a medical doctors' association, dentists' association, or oriental medical doctors' association, defined under the Medical Services Law, or by the Korean Pharmaceutical Association or the Korea Oriental Pharmacy Association, defined under the Pharmaceutical Affairs Law, as an international academy, 100 or more of whose regular members are foreigners from five (5) or more countries.⁶¹

- "Product Informational Presentation" is (i) an event held in Korea by a Company for the Healthcare Professionals of multiple medical institutions for the purpose of providing information on its own pharmaceuticals or (ii) the providing of information by a Company on its pharmaceuticals to the Healthcare Professional(s) of individual medical institutions on visits to such institutions.⁶²
- "Market Survey" is the collecting by a Company of data relating to the market and the scope and characteristics of its components, including consumer demands.⁶³
- "Post-Marketing Surveillance" is any study conducted by a Company for the collection of data on safety, efficacy, or proper use of a drug which is subject to re-examination as mandated under the Pharmaceutical Affairs Law, during the mandated re-examination

⁶¹ KPMA Code, Art. 3(8), KRPIA Code, Art. 3(8).

⁶² KPMA Code, Art. 3(9), KRPIA Code, Art. 3(9).

⁶³ KPMA Code, Art. 3(10), KRPIA Code, Art. 3(10).

period.⁶⁴

- “Money or Other Valuables” is any kind of economic benefit provided by a Company to a Medical Institution or a Healthcare Professional, including, but not limited to, goods, money, gift certificates, securities or other written promises of payment, entertainment (including food/beverage, invitation to or preferential treatment to any movie, play, or other performance or sports event, travel, golf, or ski), transportation, lodging, registration for academic conferences, labor or any other service, discounts, free goods or sales incentives (excluding discounts pursuant to terms of payment or points accumulated for the use of credit/debit cards, as permitted under the Medical Services Law or the Pharmaceutical Affairs Law).⁶⁵

D. Restriction on Providing Money or Other Valuables

The basic rule is that a Company must not provide any Money or Other Valuables to a Medical Institution or a Healthcare Professional, unless the provision of Money or Other Valuables is (i) permitted under any one of Articles 6 through 15 of the KPMA/KRPIA Codes and within the boundaries of socially accepted normal commercial practice,⁶⁶ or (ii) permitted by the Ministry of Health and Welfare pursuant to the relevant provisions in the Medical Services Law or the Pharmaceutical Affairs Law.⁶⁷

Any provision of Money or Other Valuables to a Medical Institution or a Healthcare Professional by a domestic or overseas affiliated entity of a Company, at the request of that

⁶⁴ KPMA Code, Art. 3(11), KRPIA Code, Art. 3(11); The Pharmaceutical Affairs Law mandates post-marketing surveillance for a statutorily-prescribed period of 4 or 6 years for certain types of new drugs once they are approved for marketing in Korea. The manufacturer/importer of the drug in question must collect and submit certain data to the Korea Food & Drug Administration. Pharmaceutical Affairs Law Art. 32, Art. 42(4).

⁶⁵ KPMA Code, Art. 3(12), KRPIA Code, Art. 3(12).

⁶⁶ KPMA Code, Art. 5(1), KRPIA Code, Art. 5(1).

⁶⁷ KPMA Code, Art. 5(2), KRPIA Code, Art. 5(2).

Company, or any such provision when that Company knew or could have known about it but willfully or negligently failed to prevent it is deemed a provision by that Company.⁶⁸ The same deemer clause applies to any provision of Money or Other Valuables to a Medical Institution or a Healthcare Professional by a wholesaler or marketing agency (commissioned by the Company to carry out promotional activities) at the request of or with the actual knowledge or negligent ignorance of the Company.⁶⁹ The deemer clauses, newly inserted into the KPMA/KRPIA Codes in the recent rounds of amendments represent an attempt to clamp down on the indirect provision of illicit benefits, which the KFTC pointed out as being widespread in the industry.⁷⁰

The basic rule, then, is that a pharmaceutical company cannot provide any kind of economic benefit to a healthcare professional or hospital, unless the provision falls into any of the express exceptions recognized under the KPMA/KRPIA Codes or the relevant regulations issued by the Ministry of Health and Welfare. This is considerably more stringent than the rules provided for in the PhRMA Code. The exceptions to the basic rule are discussed below.

E. Free Drug Samples

A Company may provide product samples to a Medical Institution or a Healthcare Professional, free of charge, but only for the purpose of enabling identification of such characteristics of the drug as formulation, color, taste, or scent, and only in units clearly marked as “sample”, in the minimum amount necessary for such identification.⁷¹ Accordingly, giving healthcare professionals free drug samples for any other purpose, for example, to be provided to patients, would be in violation of the KPMA/KRPIA Codes.

⁶⁸ KPMA Code, Art. 5(3), KPMA Code Working Guidelines, Art. 2(1), KRPIA Code, Art. 5(3), KRPIA Code Working Guidelines, Art. 2(1).

⁶⁹ KPMA Code, Art. 5(3), KPMA Code Working Guidelines, Art. 2(2), KRPIA Code, Art. 5(3), KRPIA Code Working Guidelines, Art. 2(2).

⁷⁰ Korea Fair Trade Commission, *supra* note 56.

⁷¹ KPMA Code, Art. 6, KPMA Code Working Guidelines, Art. 3, KRPIA Code, Art. 6, KRPIA Code Working Guidelines, Art. 3.

F. Donations

The KPMA/KRPIA Codes outline a detailed procedure which a Company must adhere to if it wishes to make a Donation for a medical/pharmacological/educational, or charitable purpose. Notwithstanding the definition of “Donation in the KPMA/KRPIA Codes, which suggests that hospitals can be recipients, the Working Guidelines to the KPMA/KRPIA Codes restrict the scope of permissible recipients to non-profit organizations established for the academic or research purposes and not subordinate to any specific hospital or medical institution.⁷² An exception is recognized for donations of drugs for charitable purposes, which can be made to hospitals and other medical institutions, subject to certain procedural requirements.⁷³

A Company that wishes to make a Donation cannot choose the recipient itself but must request the KPMA/KRPIA to select a recipient.⁷⁴ The KPMA/KRPIA is required, in selecting the recipient, to respect the donor Company’s stated purpose of the Donation and may, at its discretion, permit the donor Company to present its opinion to the KPMA/KRPIA as part of the deliberation process.⁷⁵ The actual deliberation and decision-making are tasked to an internal body within the KPMA/KRPIA, called the Code Deliberation Committee.⁷⁶ If the donor Company objects to the KPMA/KRPIA’s decision regarding the recipient, the donor Company may withdraw its request for selection of a recipient within five days of receiving notification of the KPMA/KRPIA’s decision.⁷⁷ An exception to the above procedure is recognized in cases where an organization submits a donation request to the KPMA/KRPIA to fund a project (e.g.,

⁷² KPMA Code Working Guidelines, Art. 4(1), KRPIA Code Working Guidelines, Art. 4(6).

⁷³ KPMA Code, Art. 7(4), KPMA Code Working Guidelines, Art. 4(7), KRPIA Code, Art. 7(4), KRPIA Code Working Guidelines, Art. 4(7).

⁷⁴ KPMA Code 7(1)-2, KRPIA Code 7(1)-2.

⁷⁵ KPMA Code 7(2), KRPIA Code 7(2).

⁷⁶ KPMA Code 16(1), KRPIA Code 16(1).

⁷⁷ KPMA Code Working Guidelines, Art. 4(2)-4, KRPIA Code Working Guidelines, Art. 4(2)-5.

awarding academic prizes, academic campaigns), in which case the KPMA/KRPIA, if it determines the project to be appropriate, solicits offers from potential donor Companies and chooses the donor.⁷⁸ Other than by adhering to these procedures, a Company is prohibited from making a donation directly to a medical institution or a healthcare professional.⁷⁹

Donations are not permitted if (i) a benefit has been promised relating to the formulary listing, prescription, or purchase of the donor Company's drug; (ii) the donor Company is responding to a request for a donation from the intended recipient, in consideration of potential effects on the formulary listing, prescription, or purchase of the donor Company's drug; (iii) if the Donation is intended to be used to fund real estate/equipment purchases, expansion or renovation of facilities, management, or any other expenditure that is recognized by social norms as one that should be borne by the intended recipient; or (iv) Donations are being provided repeatedly and continuously to the same recipient without justifiable cause.⁸⁰

Donations, as defined in the KPMA/KRPIA Codes, are outside the purview of the PhRMA Code. Moreover, the elaborate procedure required for a company to make a donation, involving the KPMA/KRPIA in a central role, is unlike anything provided for in the PhRMA Code. The provisions on Donations are a good example of the impact that the recent KFTC enforcement actions have had on the compliance environment in the Korean healthcare industry. As discussed above, financial donations made by companies, to hospitals in particular, were a contentious issue during the first two rounds of investigations and enforcement actions undertaken by the KFTC. Such donations were widespread in the industry and widely recognized as being tied to hospital formulary listing or purchase decisions. However, the KFTC ultimately decided not to condemn them on a per se basis, instead applying a case-by-case analysis of legality, in part because it recognized the positive role that donations play in fostering medical research.

These newly inserted provisions of the KPMA/KRPIA Codes represent an effort on the

⁷⁸ KPMA Code 7(1)-3, KRPIA Code 7(1)-3.

⁷⁹ KPMA Code 7(1)-4, KRPIA Code 7(1)-4.

⁸⁰ KPMA Code 7(1)-1, KRPIA Code 7(1)-1.

part of the industry to place donations on more solid legal footing, by reducing the possibility that donations will be abused as a means for furthering illicit business purposes. It is difficult to predict at this early stage how the effects of these provisions will play out and it is unclear whether they will bring about a sea change in companies' behavior regarding donations. By taking away from individual companies the freedom, by and large, to choose the recipients of their donations and by extension the freedom to choose more specifically how their funds will be used, these provisions run the risk of driving companies away from donations entirely. More worryingly, there is also the risk that companies will seek to abuse the safety mechanisms built into the process, for example, by exerting influence on the Code Deliberation Committee to select a recipient more suited to their purposes or, work out a tacit agreement with the preferred recipient in advance of approaching the KPMA/KRPIA with a request for selection of a recipient, so that the preferred recipient can promptly come forward once the KPMA/KRPIA starts its solicitation process.

G. Support for Holding Academic Conferences

The KPMA/KRPIA Codes outline a procedure by which Companies may provide financial support for third party academic conferences held in Korea. The organizer of the academic conference must be an organization recognized by a medical doctors' association, dentists' association, or oriental medical doctors' association, defined under the Medical Services Law, by the Korean Pharmaceutical Association or the Korea Oriental Pharmacy Association, defined under the Pharmaceutical Affairs Law, or by the KPMA/KRPIA.⁸¹

For domestic Academic Conferences, the KPMA/KRPIA, upon receiving applications for support from one such organizer, solicits offers from Companies, based on which the KPMA/KRPIA, through its Code Deliberation Committee, decides which Company will provide the requested support.⁸² In this regard, the KPMA/KRPIA may permit a Company to sponsor

⁸¹ KPMA Code 8(1), KRPIA Code 8(1).

⁸² KPMA Code 8(2), KRPIA Code 8(2).

a domestic Academic Conference only on the condition that 20% or more of the total expenses incurred be borne by the organizer.⁸³ For Domestically-held International Academic Conferences, a Company that wishes to provide support for such a conference may do so by providing prior notice to the KPMA/KRPIA of the name of the conference and the amount and particulars of the support to be provided.⁸⁴ For both types of conferences, the Company that provided support must within one month from the conclusion of the conference submit a report, in a form designated by the KPMA/KRPIA, outlining the particulars of the support provided, for verification by the KPMA/KRPIA that support was provided in compliance with the Codes.⁸⁵ The Company providing support must not be involved in any decision-making over the agenda, proceedings, participants, or related materials of the Academic Conference.⁸⁶

The KPMA/KRPIA Codes provide for greater restrictions on companies in providing support for third party academic conferences, compared with the PhRMA Code,⁸⁷ and also provide an express oversight role for the trade association that is absent in the PhRMA Code. The potential for abuse of the procedural requirements, similar to the one discussed with respect to Donations, is present here as well.

H. Support for Attendance at Academic Conferences

Companies may provide support for individual Healthcare Professionals to attend an Academic Conference held in Korea or abroad, provided that the conference is held in a manner and at a venue appropriate to an academic or educational purpose.⁸⁸ Support is permitted only for Healthcare Professionals who are presenters, chairs or panelists at the conference and for

⁸³ KPMA Code 8(3), KRPIA Code 8(3).

⁸⁴ KPMA Code Art. 8(4), KRPIA Code Art. 8(4).

⁸⁵ KPMA Code Art. 8(2), 8(4), KRPIA Code Art. 8(2), 8(4).

⁸⁶ KPMA Code Art. 8(5), KRPIA Code Art. 8(5).

⁸⁷ PhRMA Code on Interactions with Healthcare Professionals 7 (2009).

⁸⁸ KPMA Code Art. 9(2)-1, KRPIA Code Art. 9(2)-1.

actual expenses incurred for transportation, registration, meals, and lodging.⁸⁹ The Company providing the support must do so by depositing the funds for the designated Academic Conference and must not directly provide support to the organizer of the Conference or the individual Healthcare Professionals attending that conference.⁹⁰ The support provided must not be linked to any entertainment, travel, sightseeing, or leisure activities and support for the companions of Healthcare Professionals is prohibited.⁹¹ The KPMA/KRPIA must provide the Academic Conference designated by the Company with the deposited funds but may only designate the purpose and scope of the support being provided and must not designate the individual Healthcare Professionals to be supported.⁹² Since the permissible support is only for actual expense incurred, the KPMA/KRPIA must obtain from the organizer of the conference a detailed statement of actual expenses incurred for transportation, registration, meals, and lodging, along with supporting documentation, and provide the Company with the relevant information, upon which the Company will deposit the appropriate amount of funds with the KPMA/KRPIA to be delivered to the organizer of the conference.⁹³

The Working Guidelines to the KPMA/KRPIA Codes provide for very specific monetary ceilings on the support permitted. In the case of transportation costs, for Academic Conferences held overseas, the ceiling is the international flight roundtrip economy class fare for the shortest route to destination, to be determined by the confirmed price for the date of return, while for Academic Conferences held in Korea, the ceiling is the domestic flight economy class fare, KTX (Korean bullet train) second class fare, or premium express bus fare to destination, or public transportation fares equivalent to the above.⁹⁴ For meals, the ceiling is three meals per day, KRW 50,000 per bill per meal paid for with one's personal credit card or in cash during

⁸⁹ KPMA Code Art. 9(2)-2, KRPIA Code Art. 9(2)-2.

⁹⁰ KPMA Code Art. 9(2)-3, KRPIA Code Art. 9(2)-3.

⁹¹ KPMA Code Art. 9(2)-5, KRPIA Code Art. 9(2)-5.

⁹² KPMA Code Art. 9(3)-1, KRPIA Code Art. 9(3)-1.

⁹³ KPMA Code Working Guidelines Art. 6(4), KRPIA Code Working Guidelines Art. 9(4).

⁹⁴ KPMA Code Working Guidelines Art. 6(5)-1, KRPIA Code Working Guidelines Art. 9(5)-1.

meal time at a local restaurant.⁹⁵ For lodging, the ceiling is KRW 200,000 per night for domestic accommodations and KRW 350,000 per night for overseas accommodations, with support permitted starting from the day before the conference start date to the conference end date.⁹⁶

The basic principle of allowing financial support for healthcare professionals to attend academic conferences only indirectly, through the third party organizer, and prohibiting the giving of direct support to healthcare professionals, as well as allowing support for costs of travel, lodging, and other personal expenses only for substantive participants in the conference are broadly in line with the PhRMA Code's provisions on support for third party educational or professional meetings.⁹⁷ However, the KPPMA/KRPIA Codes set stringent limits on the scope of permissible support, in the form of very specific monetary ceilings.

I. Company-Hosted Product Informational Presentations

When hosting Product Informational Presentations for the Healthcare Professionals of multiple medical institutions, a Company may provide to each participating Healthcare Professional food/beverages up to KRW 100,000 in value, reimbursement for the actual costs incurred for transportation and lodging, and souvenir gifts of up to KRW 50,000 in value.⁹⁸ For Product Informational Presentations which take the form of visits to individual medical institutions, a Company may provide to each participating Healthcare Professional food and beverages up to KRW 100,000 in value, up to four times a month, and small-value brand reminders KRW 10,000 or less in value.⁹⁹ In the case of Product Informational Presentations at

⁹⁵ KPMA Code Working Guidelines Art. 6(5)-3, KRPIA Code Working Guidelines Art. 9(5)-3.

⁹⁶ KPMA Code Working Guidelines Art. 6(5)-4, KRPIA Code Working Guidelines Art. 9(5)-4.

⁹⁷ PhRMA Code on Interactions with Healthcare Professionals 7 (2009).

⁹⁸ KPMA Code Art. 10(1), KPMA Code Working Guidelines Art. 7(1), KRPIA Code Art. 10(1), KRPIA Code Working Guidelines Art. 10(1).

⁹⁹ KPMA Code Art. 10(41), KPMA Code Working Guidelines Art. 7(5), KRPIA Code Art. 10(4), KRPIA Code Working Guidelines Art. 10(5).

which lodging is to be provided to participating Healthcare Professionals, the Company hosting the event must apply to the KPMA/KRPIA for approval no later than 60 days prior to the date of the presentation and obtain prior approval.¹⁰⁰ For all other Product Informational Presentations, it suffices to give notice to the KPMA/KRPIA no later than 30 days prior to the date of the presentation.¹⁰¹ Companies must not hold Product Informational Presentations as a guise for providing food/beverages at gatherings of Healthcare Professionals.¹⁰²

Compared with the PhRMA Code's provisions on informational presentations and accompanying meals¹⁰³ and those on speaker training meetings,¹⁰⁴ the KPMA/KRPIA Codes provide for a much more rigid framework within which companies may hold informational presentations for healthcare professionals and allows for oversight by the trade association. The one area where the PhRMA Code seems to be more stringent is its prohibition on the giving of non-educational and practice-related items.¹⁰⁵

J. Post-Marketing Surveillance Studies

In conducting the statutorily mandated Post-Marketing Surveillance study, a Company must not contract with a medical institution which is not already using the drug¹⁰⁶ and must not contract on the condition that the medical institution continue to purchase or increase its purchase of the drug,¹⁰⁷ restrictions which are intended to deter companies from using payment for the studies as an inducement for the hospital or physician to start using the drug. The

¹⁰⁰ KPMA Code Art. 10(2), KRPIA Code Art. 10(2).

¹⁰¹ KPMA Code Art. 10(2), KRPIA Code Art. 10(2).

¹⁰² KPMA Code Art. 10(5), KRPIA Code Art. 10(5).

¹⁰³ PhRMA Code on Interactions with Healthcare Professionals 4 (2009).

¹⁰⁴ *Id.* at 9.

¹⁰⁵ *Id.* at 11.

¹⁰⁶ KPMA Code Art. 13(1)-2, KRPIA Code Art. 13(1)-2.

¹⁰⁷ KPMA Code Art. 13(1)-3, KRPIA Code Art. 13(1)-3.

Company must decide the number of cases for the study based on medical or pharmacological necessity pursuant to applicable laws and regulations and the number should be appropriate in light of the purpose and content of the study.¹⁰⁸ The Company may pay compensation to Healthcare Professionals who contracted to conduct the study, at a rate of up to KRW 50,000 per case report, provided that up to KRW 300,000 may be paid per case report if additional survey is required, e.g., because the study involves a rare disease as provided under the Pharmaceuticals Affairs Law or relevant regulations of the Korea Food & Drug Administration, long-term monitoring, or frequent and significant adverse effects.¹⁰⁹ The number of case reports for which the Company may provide compensation is capped at the minimum number required for post-marketing surveillance under applicable laws, i.e., 3,000 cases if the re-examination period is 6 years, and 600 cases, if 4 years.¹¹⁰ The Company must not pay the full amount of the compensation until the study has been completed and it has been apprised of the results.¹¹¹

The PhRMA Code does not have a corresponding section, particularly since the post-marketing surveillance regulated under the KPMA/KRPIA Codes is predicated on Korea's new drug approval regime. It is notable, however, that even for this statutorily-mandated activity, the KPMA/KRPIA Codes set strict limits on the amount of compensation that can be provided to healthcare professionals, both at the individual recipient level (i.e., compensation ceiling per case report) and at the company expenditure level (i.e., number of cases).

K. Other Clinical Studies

In addition to the statutorily-mandated post-marketing surveillance studies, which is a very narrow category by definition, a Company may undertake other clinical studies for the purpose of obtaining medically or pharmaceutically important information on clinical

¹⁰⁸ KPMA Code Art. 13(1)-1, KRPIA Code Art. 13(1)-1.

¹⁰⁹ KPMA Code Working Guidelines Art. 9(1), KRPIA Code Working Guidelines Art. 13(1).

¹¹⁰ KPMA Code Art. 13(1)-5, KRPIA Code Art. 13(1)-5.

¹¹¹ KPMA Code Art. 13(1)-5, KRPIA Code Art. 13(1)-5.

characteristics of pharmaceuticals, diseases, or other healthcare fields of significant interest to the Company, pursuant to applicable provisions in the Pharmaceuticals Affairs Law and Korean Food and Drug Administration regulations.¹¹² The study must be approved by the Korean Food and Drug Administration or by the relevant hospital institutional review board, depending on the type of study.¹¹³ The Company may provide compensation for the work done by Healthcare Professionals participating in the study, but not direct payment to the individual Healthcare Professionals is prohibited.¹¹⁴ The Company must contract with and make any payment to the medical institution at which the Healthcare Professionals are employed.¹¹⁵ As in the case of statutorily-mandated post-marketing surveillance studies, the Company must not pay the full amount of the compensation until the study has been completed and it has received a report of the results.¹¹⁶

The PhRMA Code does not have a corresponding section on clinical activities and PhRMA has chosen instead to address member companies' interactions with clinical investigators and others as they relate to the clinical research process in a separate set of guidelines.¹¹⁷ The fact that the KPMA/KRPIA has chosen to regulate clinical research activities as part of its code on marketing and that the KFTC has endorsed this approach underlines the how such activities have been perceived to date both inside and outside the industry and the degree to which they have been abused for improper purposes.

L. Exhibits and Advertising

¹¹² KPMA Code Art. 14(1), KRPIA Code Art. 14(1).

¹¹³ KPMA Code Art. 14(1)-1, KRPIA Code Art. 14(1)-1.

¹¹⁴ KPMA Code Art. 14(1)-3, KRPIA Code Art. 14(1)-3.

¹¹⁵ KPMA Code Art. 14(1)-3, KRPIA Code Art. 14(1)-3.

¹¹⁶ KPMA Code Working Guidelines Art. 10(1), KRPIA Code Working Guidelines Art. 14(1).

¹¹⁷ PhRMA Code on Interactions with Healthcare Professionals 3 (2009).

Companies may put on exhibits and place advertisements targeted at Healthcare Professionals in order to disseminate medical/pharmacological knowledge and maximize benefits to patients.¹¹⁸ Companies may purchase booths at academic conferences organized by medical institutions or academic organizations or place advertisements in publications issued or websites operated by such entities, provided that the payments for booths or advertisements accord with normal commercial practices.¹¹⁹ The Working Guidelines specify what is considered to be within the boundaries of “normal commercial practices”, but the KPMA and the KRPIA versions differ slightly in this regard with respect to payments for booths.

The KPMA differentiates between academic conferences organized by academic/research organizations and those organized by hospitals or other medical institutions. For the former, the permissible standard payment is KRW 2 million per booth, but payments up to KRW 3 million per booth may be allowed in light of such factors as the characteristics and scale of and the number of attendees at the conference.¹²⁰ For the latter, the permissible standard payment is KRW 500,000 per booth, but payments up to KRW 1 million per booth may be allowed in light of similar factors.¹²¹ The KRPIA likewise differentiates between these two categories of conferences, but with a limit of KRW 3 million per booth for academic conferences organized by academic/research organizations and KRW 1 million per booth for those organized by hospitals or other medical institutions.¹²² Both the KPMA and the KRPIA limit the number of booths that can be purchased to one per conference and in any case prohibit the purchase of more than two booths.¹²³

With respect to advertisements placed on websites of academic/research organizations, the limit is KRW 10 million per year in advertising fees, with a monthly limit of KRW 1 million.

¹¹⁸ KPMA Code Art. 15(1), KRPIA Code Art. 15(1).

¹¹⁹ KPMA Code Art. 15(3), KRPIA Code Art. 15(3).

¹²⁰ KPMA Code Working Guidelines Art. 11(1)-5.

¹²¹ KPMA Code Working Guidelines Art. 11(1)-5.

¹²² KRPIA Code Working Guidelines Art. 15(1)-4.

¹²³ KPMA Code Working Guidelines Art. 11(1)-4, KRPIA Code Working Guidelines Art. 15(1)-4.

For print media, the permissible advertising fee range is from KRW 600,000 to 1.5 million for media published by hospitals or other medical institutions and from KRW 700,000 to 2 million for those published by academic/research organizations.¹²⁴ Payment for advertising is not permitted for print media that has been independently produced by Healthcare Professionals or print media published by a hospital and intended only for distribution to employees of that hospital.¹²⁵

This is another area of activity that is not dealt with in the PhRMA Code. Again, the KPMA/KRPIA Codes have taken a very rigid approach, specifying the permissible number and price of booths that may be purchased by companies as well as the pricing of advertising.

M. Implementation and Adherence to the Codes

The KPMA/KRPIA Codes provide for a Code Deliberation Committee (“CDC”) to be constituted within the KPMA/KRPIA, comprising 10 members, 5 of whom are to be selected from outside the KPMA/KRPIA – 2 nominated by the Korea Consumer Agency,¹²⁶ 1 by the National Health Insurance Corporation,¹²⁷ and 2 by the Korean Medical Association.¹²⁸ The quorum is 2/3 of all members in attendance and decisions are reached by agreement of the majority of the members present.¹²⁹ It seems that the outside members are intended to ensure that the interests of consumers (as consumers of drugs), the government (as payer for drugs), and the medical community (as prescribers of drugs) are sufficiently reflected in the CDC’s deliberations.

Under the KPMA Code, the CDC is authorized to deliberate on and decide the following:

¹²⁴ KPMA Code Working Guidelines Art. 11(1)-3, KRPIA Code Working Guidelines Art. 15(1)-3.

¹²⁵ KPMA Code Working Guidelines Art. 11(1)-2, KRPIA Code Working Guidelines Art. 15(1)-2.

¹²⁶ The country’s primary consumer protection agency.

¹²⁷ A public corporation tasked with administering the country’s National Health Insurance Program.

¹²⁸ KPMA Code Art. 16(2), KRPIA Code Art. 16(2).

¹²⁹ KPMA Code Art. 16(3), KRPIA Code Art. 16(3).

(i) selection of recipients for Donations proposed by Companies, selection of donor Companies for Donations requested by academic/research organizations, determination of whether the Donations were carried out appropriately; (ii) determination of whether support requests from organizers of Academic Conferences are appropriate and if so, which Companies will provide the support, determination of whether support was provided appropriately; (iii) investigation into alleged violations of the Code; (iv) matters related to the adoption of and amendments to the Working Guidelines to the Code; and (v) other matters related to the Code regarding which the KPMA has requested deliberation.¹³⁰ Under the KRPIA Code, the CDC has authority to deliberate on and decide all of the above matters, plus the authority to approve Product Informational Presentations and determine whether they are appropriate and to provide an authoritative interpretation in response to inquiries from member Companies regarding whether specific activities are in compliance with the Code.¹³¹

When there is an allegation of a member Company violating the Code, the CDC must investigate the allegation.¹³² Member Companies are obligated to cooperate with the CDC's investigation and against an uncooperative member Company, the CDC may impose a monetary penalty of up to KRW 5 million and request the KFTC for necessary action.¹³³

Under the KPMA Code, when the CDC determines that a member Company has violated the Code, the CDC may (i) issue a warning, (ii) impose a monetary penalty of up to KRW 10 million (applicable if the violation is clear and risks damaging the reputation of the pharmaceutical industry), or (iii) impose a monetary penalty of up to KRW 100 million, file a complaint with the relevant authorities, and request expulsion of the member Company from the KPMA (applicable if the violation is clear and serious and may be subject to legal sanctions).¹³⁴ In addition, in the event the member Company does not comply with any of the above actions,

¹³⁰ KPMA Code Art. 16(1).

¹³¹ KRPIA Code Art. 16(1).

¹³² KPMA Code Art. 17(1), KRPIA Code Art. 17(1).

¹³³ KPMA Code Art. 17(2), 17(3), KRPIA Code Art. 17(2), 17(3).

¹³⁴ KPMA Code Art. 18(1), 18(2), 18(3).

the CDC may request the KFTC and the Ministry of Health and Welfare for necessary action.¹³⁵

The KRPIA Code provides for a slightly different enforcement mechanism. When the CDC determines that a member Company has violated the Code, the CDC must issue a written decision ordering the Company to take corrective action.¹³⁶ Within 15 days from the receipt of the written decision, the Company must provide the CDC with a written statement of the corrective action it has already undertaken or plans to undertake.¹³⁷ If the Company does not comply with the corrective action, the CDC may notify the KFTC and the Ministry of Health and Welfare of the Company's action violating the Code and in addition, (i) impose a monetary penalty of up to KRW 100 million, (ii) expel the Company from the KRPIA, or (iii) notify the top management of the Company's parent.¹³⁸

Both the KPMA and KRPIA Codes provide for a limited internal appeal process, through which a member Company may challenge an adverse decision undertaken by the CDC.¹³⁹ The KPMA/KRPIA Codes also provide for mandatory document retention for a period of 5 years for materials submitted by the member Companies to the KPMA/KRPIA as required by the Codes with respect to the activities they regulate as well as materials relating to any CDC investigation and disposition relating to an alleged violation.¹⁴⁰ The KPMA/KRPIA must respond in good faith with any request from the KFTC or the Ministry of Health and Welfare for production of documents thus retained.¹⁴¹ Any amendment to the KPMA/KRPIA Code requires prior review and approval by the KFTC.¹⁴²

Based on the above provisions that allow KFTC involvement in implementation and

¹³⁵ KPMA Code Art. 18(4).

¹³⁶ KRPIA Code Art. 18(1).

¹³⁷ KRPIA Code Art. 18(2).

¹³⁸ KRPIA Code Art. 18(3).

¹³⁹ KPMA Code Art. 21, KRPIA Code Art. 21.

¹⁴⁰ KPMA Code Art. 20(1), KRPIA Code Art. 20(1).

¹⁴¹ KPMA Code Art. 20(2), KRPIA Code Art. 20(2).

¹⁴² KPMA Code Art. 23, KRPIA Code Art. 23.

enforcement of the KPMA/KRPIA Codes, the KFTC's role as overseer of the relationship between the industry and healthcare professionals has been institutionalized. Accordingly, seems very likely that the KFTC will continue to play a leading role in this area, at least in the short to medium-term, particularly since the other government agencies, now armed with their own tools of enforcement but lacking concrete standards to apply in determining whether violations have occurred, can be expected to look to the KPMA/KRPIA Codes and KFTC practice as benchmarks in their efforts.

V. Conclusion

The KPMA and the KRPIA have responded to the drastically changed compliance environment facing the Korean pharmaceutical industry by coming up with a very complicated and stringent set of guidelines, likely in the hope that the litany of new obligations and restrictions will become a mantra of good behavior for the companies, perhaps enough to restore the industry to good graces in the eyes of the authorities.

Leaving aside the potentially troubling question of how much support the new Codes enjoy among the member companies at large, the new KPMA/KRPIA Codes reveal themselves to be problematic in many ways, perhaps more so if companies endeavor to follow them to the letter. They will likely impose a huge administrative burden on companies in terms of time and money costs, since they will be obligated to meet the myriad reporting and supporting document submission requirements, as well as abide by more elaborate procedures if they wish to undertake any donations or support for academic conferences. This burden may very well divert valuable human and capital resources away from and sap the corporate energy that could be channeled towards worthwhile pursuits such as R&D. It is worth noting that the new Codes have gone into effect at a time of discernible "investigation fatigue," as companies and people within the industry members feel constantly besieged and berated, negatively affecting the morale of existing talent and hindering efforts to recruit fresh talent.

As the Ministry of Health and Welfare emphasized, the Korean pharmaceutical industry

needs to root out corrupt practices and increase transparency as a whole if it is to become more competitive. The KPMA/KRPIA Codes, however, appear to be putting the cart before the horse, defining compliance narrowly, often within arbitrary boundaries, as if keeping the price of a meal or a souvenir under a specific ceiling is an end in itself instead of an imperfect means to an end.

If the KPMA/KRPIA Codes are enforced to the letter, there appears to be the danger that kickbacks will be driven underground, as companies stay away from promotional activities so strictly regulated under the Codes and rely more on cash and other illicit gifts. This would be doubly negative, because the activities regulated under the Codes have very real value as tools for the dissemination of information and knowledge that can benefit patients and this value would be lost if companies turn away from these activities.

There is also the question of whether the KFTC is the right agency to continue leading government enforcement in this arena. It is a competition authority, but competition (at least not of the traditional variety on price or quality of products) is not a hallmark of the pharmaceutical market in Korea. This market behaves very differently in many ways from most other markets, with fixed prices (for drugs reimbursable under the National Health Insurance Program, the government sets the price) and end-consumers who are not permitted to choose products they consume, and payers who do not get to choose, either.

The new KPMA/KRPIA Codes have only just become effective and may be subject to yet more revisions in the days to come. So it is still too early to predict with any degree of accuracy how the new requirements will play out and what impact it will have on the industry in the short and long term. However, it is safe to assume that compliance will continue to dominate the industry's agenda for many years to come, as the pharmaceutical industry in Korea enters a brave new world.